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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/763,329	07/09/2001	Joachim Messing	13259-00011	4832

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EXAMINER	
MEHTA, ASHWIN D	
ART UNIT	**PAPER NUMBER**
1638	10

DATE MAILED: 01/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,329	MESSING ET AL.	
	Examiner	Art Unit	
	Ashwin Mehta	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9 .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicants' election of Group I, claims 1-18 in Paper No. 8, received 04 November 2002, is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. **NOTE:** An error appears in the numbering of the claims. A claim numbered 14 is missing, and there are two claims numbered 15. Applicants are notified that the first of the claims numbered 15 has been renumbered as claim 14, in accordance with 37 CFR 1.126.

Priority

3. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The sentence should indicate that the instant application is the U.S. national stage filing of PCT/US99/20308, which is claims benefit to U.S. provisional applications 60/098,034 and 60/137,836.

Specification

4. The bibliographic reference cited on page 25, lines 1-3 (Timmermans et al.) is incomplete, and within the list of references provided on pages 31-34). Applicant should review the specification to ensure that all other bibliographic references are complete.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1 and 5-7 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claims are broadly drawn towards any DNA construct encoding any δ-zein, comprising any δ-zein coding sequence operably linked to any promoter and to any sequence encoding a 3' untranslated region (UTR) that is modified so that it is devoid of binding sites for any dzr1 negative regulatory protein; or wherein said δ-zein is selected from the group consisting of any 10 kDa zein and any 18 kDa zein; or wherein said promoter is seed-specific.

The claims read on a DNA construct, including those found in nature and thus, is unpatentable to applicant. The DNA construct as claimed, has the same characteristics as those found naturally in the genome or as cellular precursors thereof and therefore does not constitute patentable subject matter. See American Wood v. Fiber Disintegrating Co., 90 U.S. 566 (1974), American Fruit Growers v. Brodgex Co., 283 U.S. 2 (1931), Funk Brothers Seed Co. v. Kalo Inoculant Co., 33 U.S. 127 (1948), Diamond v. Chakrabarty, 206 USPQ 193 (1980). It is

suggested that claim 1 be amended by inserting the term "isolated" before "DNA", to identify a product that is not found in nature.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1: the recitation "a modified 3' untranslated region (UTR), the 3' UTR being modified so as to be devoid of binding sites for a dzr1 negative regulatory protein" in lines 3-6 renders the claims indefinite. It is not clear if unmodified 3' UTRs that do not contain a dzr1 binding site are encompassed by the claim. The metes and bounds of the claim are not clear.

In claim 2: the claim recites the limitation "the dzr1 binding site-containing 3' UTR" in line 3. There is insufficient antecedent basis for this limitation in the claim or parent claim1.

In claim 18: the claim recites the limitation "the chimeric gene of claim 11" in line 4. There is insufficient antecedent basis for this limitation. Claim 11, nor parent claim 1, mentions a chimeric gene. Further, claim 11 is directed to a method, not a chimeric gene.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn towards any DNA construct encoding any δ-zein, comprising any δ-zein coding sequence operably linked to any promoter and to any sequence encoding a 3' untranslated region (UTR) that is modified so that it is devoid of binding sites for any dzr1 negative regulatory protein; or wherein the modified 3' UTR is produced by site-directed mutagenesis; or wherein said δ-zein is selected from the group consisting of any 10 kDa zein and any 18 kDa zein; or wherein said promoter is seed-specific; a vector for transforming plant cells comprising said DNA construct; any plant cell transformed with said vector; any fertile, transgenic plant regenerated from said transformed cell; a method of making high methionine corn seeds comprising producing a fertile transgenic corn plant expressing said DNA construct and harvesting its seeds; a chimeric gene comprising any 10 kDa zein coding sequence from any source; a vector or transgenic corn plant comprising said chimeric gene; a method of making high methionine corn seeds comprising producing a fertile transgenic corn plant expressing said chimeric gene.

The specification teaches that a maize hybrid produced by crossing varieties BSSS53 and Mo17 has a 5-fold enrichment of methionine in the prolamin fraction as compared to the reciprocal cross, and that the increase in methionine was due to increased expression of the 10

kDa delta zein protein of maize (page 3, lines 22-33). The specification teaches that the lower expression level of the 10 kDa zein in Mo17 was due to mRNA accumulation rather than transcription, and that this differential expression was found to be due to different alleles of the dzr1 gene; that heteroallelic combinations of drz1 alleles result in reduced 10 kDa zein mRNA levels, indicating that the drz1+Mo17 allele is dominant negative, and that the presence of this allele in Mo17 and other inbred varieties will have reduced expression of the 10 kDa zein (specification, page 4, lines 17-31). The specification indicates that drz1 influences the accumulation of the 10 kDa zein mRNA by presumably interacting with the 3' UTR of the mRNA (page 14, lines 13-20). The specification teaches the construction of a plant transformation vector in which the coding sequence of the maize 10 kDa zein is operably linked to the 27 kDa zein gene promoter and the CaMV 35S 3' polyA sequence. Transgenic maize plants comprising the vector were produced. The transgenic plants exhibited a higher level of expression of the 10 kDa zein as compared to non-transgenic Mo17. Progeny of crosses between the transgenic plant and Mo17 expressed high levels of the 10 kDa zein regardless of the direction of the cross (pages 24-29, Examples 1-5).

However, the only modification of any 3-UTR described by the specification is the replacement of the entire 3'UTR of the maize 10 kDa delta zein gene. The specification does not describe any other modifications of the sequences of any 3' UTRs of any gene. The specification does not describe the sequences of the 3' UTR of the maize 10 kDa zein gene that form the binding sites of the dzr1 protein. As the specification does not describe this binding site, it does not describe how binding site within the 3' UTR can be removed. Further, the specification does not describe any other 3' UTR of any other gene that contains a dzr1 binding

site. As other 3' UTRs containing dzr1 binding sites are not described, modified 3' UTRs devoid of the binding site are not described either.

Furtherstill, while the specification indicates that two maize delta zein genes, encoding 10 and 18 kDa proteins, have been cloned (page 2, lines 13-16), DNA constructs comprising other delta zein coding sequences are not described. See Fiers vs. Sugarno, 25 USPQ 2d (CAFC 1993) at 1606, which states that "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." Given the breadth of the claims encompassing any modified 3'UTR, of any gene, devoid of binding sites for any dzr1 negative regulatory protein, and any delta zein coding sequence from any source, and the lack of written description as discussed above, the specification fails to provide an adequate written description of the multitude of promoter sequences encompassed by the claims.

8. Claims 1-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling DNA constructs comprising a modified 3'UTR that is a replacement of the maize 10 kDa delta zein gene 3' UTR with a heterologous 3' UTR, does not reasonably provide enablement for any other modified 3' UTR devoid of binding sites for dzr1 negative regulatory proteins, and all other delta zein coding sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/use the invention commensurate in scope with these claims.

The claims are broadly drawn towards any DNA construct encoding any δ-zein, comprising any δ-zein coding sequence operably linked to any promoter and to any sequence

encoding a 3' untranslated region (UTR) that is modified so that it is devoid of binding sites for any dzr1 negative regulatory protein; or wherein the modified 3' UTR is produced by site-directed mutagenesis; or wherein said δ-zein is selected from the group consisting of any 10 kDa zein and any 18 kDa zein; or wherein said promoter is seed-specific; a vector for transforming plant cells comprising said DNA construct; any plant cell transformed with said vector; any fertile, transgenic plant regenerated from said transformed cell; a method of making high methionine corn seeds comprising producing a fertile transgenic corn plant expressing said DNA construct and harvesting its seeds; a chimeric gene comprising any 10 kDa zein coding sequence from any source; a vector or transgenic corn plant comprising said chimeric gene; a method of making high methionine corn seeds comprising producing a fertile transgenic corn plant expressing said chimeric gene.

The specification teaches that a maize hybrid produced by crossing varieties BSSS53 and Mo17 has a 5-fold enrichment of methionine in the prolamin fraction as compared to the reciprocal cross, and that the increase in methionine was due to increased expression of the 10 kDa delta zein protein of maize (page 3, lines 22-33). The specification teaches that the lower expression level of the 10 kDa zein in Mo17 was due to mRNA accumulation rather than transcription, and that this differential expression was found to be due to different alleles of the dzr1 gene; that heteroallelic combinations of drz1 alleles result in reduced 10 kDa zein mRNA levels, indicating that the drz1+Mo17 allele is dominant negative, and that the presence of this allele in Mo17 and other inbred varieties will have reduced expression of the 10 kDa zein (specification, page 4, lines 17-31). The specification indicates that the dzr1 gene product influences the accumulation of the 10 kDa zein mRNA by presumably interacting with the 3'

UTR of the mRNA (page 14, lines 13-20). The specification teaches the construction of a plant transformation vector in which the coding sequence of the maize 10 kDa zein is operably linked to the 27 kDa zein gene promoter and the CaMV 35S 3' polyA sequence. Transgenic maize plants comprising the vector were produced. The transgenic plants exhibited a higher level of expression of the 10 kDa zein as compared to non-transgenic Mo17. Progeny of crosses between the transgenic plant and Mo17 expressed high levels of the 10 kDa zein regardless of the direction of the cross (pages 24-29, Examples 1-5).

The specification indicates that modification of the 3' UTR of a gene includes replacing it altogether (sentence bridging pages 13-14). However, the specification does not teach how else the 3' UTR of the maize 10 kDa zein gene, or of any other gene, can be modified to be devoid of all dzr1 binding sites. The specification admits that the sites within the 10 kDa zein mRNA sequence that is recognized by dzr1 are not known (page 16, lines 21-25). It is not clear how one skilled in the art can eliminate a binding site when the binding site itself is unknown. Further, the specification admits that it is unknown whether dzr1 encodes an RNA-binding protein (page 16, lines 11-13). It is then further unclear how one skilled in the art can modify a 3' UTR so that it no longer contains a dzr1 binding site, when it is not even known if any 3' UTR of any gene contains a dzr1 binding site in the first place. See Genentech, Inc. V. Novo Nordisk, A/S, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Further, while the specification indicates that two maize delta zein genes, encoding 10 and 18 kDa proteins, have been cloned (page 2, lines 13-16), the specification does not teach DNA constructs comprising other delta zein coding sequences and delta zein coding sequences

from other sources, as encompassed by the claims. See In re Bell, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and In re Deuel, 34 UPSQ2d, 1210 (Fed. Cir. 1995), which teach that the mere existence of a protein does not enable claims drawn to a nucleic acid encoding that protein. See also Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016 at 1021 and 1027, (Fed. Cir. 1991) at page 1021, where it is taught that a gene is not reduced to practice until the inventor can define it by "its physical or chemical properties" (e.g. a DNA sequence).

Furtherstill, the specification does not teach that methionine content of corn seeds can be increased by linking the coding sequence of other delta zeins, such as that encoding the maize 18 kDa zein, to the 3' UTR modified to remove dzr1 binding sites. The specification clearly teaches that it is the maize 10 kDa zein transcript that is negatively regulated by dzr1. There is no teaching at all in the specification or the prior art that dzr1 affects the expression of the any other delta zein. Swarup et al. (Plant J., 1995, Vol. 8, pages 359-368) also teach that levels of the 10 and 18 kDa delta zeins in various corn lines do not correlate with each other, indicating that they are not regulated by the same mechanism (page 365). As dzr1 affects only the maize 10 kDa delta zein expression, operably linking other delta zein coding sequences to a modified 3' UTR that is devoid of dzr1 binding sites would not affect the level of their expression, and would not increase methionine content in corn seeds. Given the breadth of the claims encompassing all 3'UTRs modified any way such that they are devoid of dzr1 binding sites, coding sequences for all delta zeins from all sources, and increasing the methionine content of corn seeds by expressing a DNA construct comprising the coding sequence for delta zeins that do not naturally contain dzr1 binding sites, unpredictability of the art and lack of guidance of the specification as

discussed above, undue experimentation would be required by one skilled in the art to make and use the claimed invention.

9. Claim 16 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim is directed towards a specific vector construct, pJM2710.

The invention appears to employ a novel plasmid, pJM2710. Since the plasmid is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plasmid is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plasmid. The specification does not disclose a repeatable process to obtain the plasmid and it is not apparent if the plasmid is readily available to the public. Thus, a deposit is required for enablement purpose. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit will not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,

(e) the deposit will be replaced if it should ever become inviable.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

10. Claims 1, 2, 5, 8-10, and 12 are rejected under 35 U.S.C. 102(e) as being anticipated by Bagga et al. (U.S. Patent No. 5,990,384).

The claims are broadly drawn towards any DNA construct encoding any δ-zein, comprising any δ-zein coding sequence operably linked to any promoter and to any sequence encoding a 3' untranslated region (UTR) that is modified so that it is devoid of binding sites for any dzr1 negative regulatory protein; or said construct wherein the modified 3' UTR is produced by replacing the 3' UTR; a vector, comprising said DNA construct, for transforming any plant cell; any plant cell transformed with said vector; any fertile, transgenic plant regenerated from said transformed cell; a chimeric gene comprising a 10 kDa zein coding sequence operably linked to a promoter and a heterologous 3' UTR.

Bagga et al. teach fertile transgenic plants that were regenerated from plant cells that were transformed with a vector comprising a DNA construct that comprised the coding sequence of a maize 10 kDa zein operably linked to the CaMV 35S promoter and the NOS terminator. Seeds of the transgenic plant were germinated, and seedlings grown. Plants for human consumption, which have been transformed to express proteins that enhance the protein quality of the plant for improved nutrition, may be transformed with the DNA construct (Figures 2C and 3A, col. 6, lines 20-23; col. 8, lines 25-52; col. 10, line 49 to col. 11, line 60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 1-3, 5, 8-12, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bagga et al. (U.S. Patent No. 5,990,384) in combination with Hirt et al. (Curr. Genet., 1990, Vol. 17, pages 473-479) and Gordon-Kamm et al. (Plant Cell, 1990, Vol. 2, pages 603-618).

The claims are broadly drawn towards any DNA construct encoding any δ-zein, comprising any δ-zein coding sequence operably linked to any promoter and to any sequence encoding a 3' untranslated region (UTR) that is modified so that it is devoid of binding sites for any dzr1 negative regulatory protein; or said construct wherein the modified 3' UTR is produced by replacing the 3' UTR; a vector, comprising said DNA construct, for transforming any plant cell; any plant cell transformed with said vector; any fertile, transgenic plant regenerated from said transformed cell; a chimeric gene comprising a 10 kDa zein coding sequence operably linked to a promoter and a heterologous 3' UTR; a method of making high methionine corn seeds comprising producing a fertile transgenic corn plant expressing said DNA construct or said chimeric gene and harvesting its seeds.

Bagga et al. is discussed above.

Bagga et al. do not teach the CaMV 35S gene 3' UTR or transformation of maize.

Hirt et al. teach the 3' UTR of the CaMV 35S gene and assert that it has been used extensively to express foreign genes in different plant species (page 474).

Gordon-Kamm et al. teach a method of obtaining fertile, stably transformed maize plants (pages 604-610).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to modify the production of transgenic plants expressing a delta zein protein of Bagga et al. by operably linking the coding sequence of the delta zein to other heterologous 3' UTRs. Any heterologous 3' UTR known in the art may have been used, including the CaMV 35S terminator taught by Hirt et al. One would have been motivated to use this terminator given that it has been successfully used to express many foreign genes in different plant species, as asserted by Hirt et al. It also would have been obvious to introduce the DNA construct comprising the delta zein coding sequence into maize plants using any suitable transformation method, for example the method taught by Gordon-Kamm et al. It would have been obvious to collect seed of the transformed maize plant, as it would contain a high concentration of methionine due to the expression of the transgenic delta zein coding sequence. One would have been motivated to introduce the DNA construct into maize plants, given the teaching of Bragga et al. that it can be introduced into plants for human consumption and to enhance the protein quality of the plant for improved nutrition.

12. Claims 1-3, 5-15, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kirihara et al.(Mol. Gen. Genet., 1988, Vol. 211, pages 477-484) in combination with Russell et al. (Trans. Res., Vol. 6, 1997, pages 157-168), and Hirt et al. (Curr. Genet., Vol. 17, 1990, pages 473-479).

Kirihara et al. teach the coding region for the maize 10 kDa delta zein protein. Kirihara et al. also assert that agriculturally important seed crops storage protein expression directly affects nutritional quality, that in maize the zein fraction of storage proteins comprise over 50% of the

total protein in the mature seed. Kirihara et al. also teach that the 10 kDa zein is distinguished by its extremely high methionine content (pages 477,480-481).

Kirihara et al. do not teach transgenic maize plants, seed-specific promoters, or 3' UTRs.

Russell et al. teach seed specific promoters, including the maize 27 kDa zein gene promoter, and the production of transgenic maize plants. The transgenic plants were used in crosses to obtain progeny, which indicates that the transgenic plants were fertile (pages 158-165).

Hirt et al. teach the 3' UTR of the CaMV 35S gene and assert that it has been used extensively to express foreign genes in different plant species (page 474).

It would have been obvious and within the scope of one of ordinary skill in the art at the time the invention was made to operably link the coding sequence of the 10 kDa zein protein of Kirihara et al. to an endosperm promoter of Russell et al., including the 27 kDa zein gene promoter, and a 3' UTR, such as the CaMV 35 gene terminator of Hirt et al., introduce this construct into maize plants. It is obvious that expression of the 10 kDa zein in the transgenic seed would increase its methionine content, as Kirihara et al. teach that it has an extremely high methionine content. One would have obviously been motivated to use a seed-specific promoter , such as the 27 kDa zein promoter of Russell et al., given that the 10 kDa zein protein is a seed storage protein. One would have been motivated to use the CaMV 35S gene terminator, given that is has been successfully used to express foreign gene in many plant species, as asserted by Hirt et al. One would have been motivated to express the 10 kDa zein coding sequence in corn seeds, given that is was known in the art, as asserted by Kirihara et al., that zein proteins

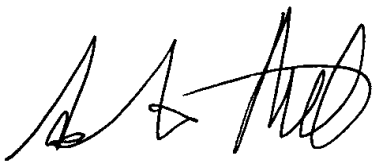
comprise over 50% of the total proteins in mature seeds, and that storage protein expression directly affects nutritional quality.

13. Pending claims 1-18 are rejected.

Contact Information

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

January 9, 2003



ASHWIN D. MEHTA, PH.D
PATENT EXAMINER